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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,779	09/23/2004	Yoshihiko Masaki	40072-0011	8473
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HELLER EHRMAN WHITE & MCAULIFFE LLP 1717 RHODE ISLAND AVE, NW WASHINGTON, DC 20036-3001			EXAMINER STITZEL, DAVID PAUL	
			ART UNIT	PAPER NUMBER

1616

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/508,779

Applicant(s)

MASAKI ET AL.

Examiner

David P. Stitzel, Esq.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/23/04</u> . | 6) <input type="checkbox"/> Other: ____. |

OFFICIAL ACTION

Status of Claims

Claims 1-17 are currently pending and therefore examined herein on the merits for patentability.

Claim Rejections - 35 U.S.C. §§ 101 and 112, Second Paragraph

The following are quotations of 35 U.S.C. §§ 101 and 112, second paragraph, respectively, which form the basis of the claim rejections as set forth under this particular section of the Official Action:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-17 are rejected under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any active, positive steps involved in the method or process, results in an improper process claim under 35 U.S.C. § 101. See e.g., *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 149 USPQ 475 (D.D.C. 1966). In addition, claims 12-17 are also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention, because a claim is rendered indefinite when said claim merely recites a use without any active, positive steps delimiting how this use is actually practiced. See MPEP 2175.03(q). More specifically, claims 12-17 provide for the use of an inulin type fructan in the manufacture of a composition, but because said claims do not set forth any steps involved in the

method or process, it is unclear what method or process Applicants are intending to encompass. As a result, the Applicants are required to either cancel or redraft the aforementioned use claims as statutory process claims that delimit active, positive steps on how to use a composition according to the invention as originally filed.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102, which forms the basis of the anticipation rejections as set forth under this particular section of the Official Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4, 7 and 12-17 are rejected under 35 U.S.C. § 102(b) as being anticipated by Japanese Application Publication 07-099965 (hereinafter the Matsumoto '965 publication).

With respect to claims 1-4 and 7 of the instant application, the Matsumoto '965 publication discloses a composition for protecting animal cells from frost damage comprising either an inulin fructan having a degree of polymerization of from 3 to 6, or a mixture of two or more inulin fructans; wherein said inulin fructan is selected from the group consisting of: 1-kestose having a degree of polymerization of 3; nistose having a degree of polymerization of 4; and tosyl nistose having a degree of polymerization of 5 (Detailed Description: [0001], [0003], [0005], [0006], [0008], [0010]-[0014], [0016]-[0019], [0021]-[0022], [0024], [0026]; Industrial Application; Effect of the Invention; Means for Solving the Problem: [0012]; Example: [0016]-[0019], [0021]-[0022], [0024], [0026]; Claims: 1-7). With respect to claims 1-4 and 7 of the

instant application, the recitation "for organ preservation" has been given little probative patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 190 USPQ 15 (CCPA 1976); and *Kropa v. Robie*, 88 USPQ 478, 481 (CCPA 1951).

With respect to claim 7 of the instant application, a recitation of an intended future use of the claimed invention must result in a patentably distinct difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art composition is capable of performing the intended use of the claimed invention, then the prior art composition anticipates the claimed invention. Since the Matsumoto '965 publication discloses a composition containing ingredients identical to those of the instantly claimed invention, the prior art composition is capable of performing the intended future use of the instantly claimed invention. As a result, the Matsumoto '965 publication anticipates said claims.

Although use claims 12-17 of the instant application are rejected under in 35 U.S.C. §§ 101 and 112 hereinabove as being drawn to non-statutory process claims, which recite a use without any active, positive steps delimiting how this use is actually practiced, thereby rendering said claims indefinite because it is unclear what method or process the Applicants are intending to encompass, for examination purposes, said use claims will be interpreted as methods for making a composition. With respect to claims 12-17 of the instant application, the Matsumoto '965 publication discloses a method of making a composition comprising either an inulin fructan having a degree of polymerization of from 3 to 6, or a mixture of two or more inulin fructans;

wherein said inulin fructan is selected from the group consisting of: 1-kestose having a degree of polymerization of 3; nistose having a degree of polymerization of 4; and tosyl nistose having a degree of polymerization of 5, wherein said method comprises purifying Meiologo G, which comprises an inulin fructan mixture present in an amount from about 55% by weight to about 60% by weight and containing inulin fructans having a degree of polymerization of from 3 to 6, by column chromatography to produce Meiologo P containing an inulin fructan and/or mixture of inulin fructans present in an amount of about 95% by weight, wherein said inulin fructan or mixture thereof comprises an inulin fructan selected from the group consisting of: 1-kestose having a degree of polymerization of 3; nistose having a degree of polymerization of 4; and tosyl nistose having a degree of polymerization of 5 (Detailed Description: [0001], [0003], [0005], [0006], [0008], [0010]-[0014], [0016]-[0019], [0021]-[0022], [0024], [0026]; Industrial Application; Effect of the Invention; Means for Solving the Problem: [0012]; Example: [0016]-[0019], [0021]-[0022], [0024], [0026]; Claims: 1-7). With respect to claims 12, 16 and 17 of the instant application, a recitation of an intended future use of the claimed invention must result in a patentably distinct difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art composition is capable of performing the intended use of the claimed invention, then the prior art composition anticipates the claimed invention. Since the Matsumoto '965 publication discloses a composition containing ingredients identical to those of the instantly claimed invention, the prior art composition is capable of performing the intended future use of the instantly claimed invention. As a result, the Matsumoto '965 publication anticipates said claims.

2. Claims 1, 7-11, 12, 16 and 17 are rejected under 35 U.S.C. § 102(b) as being anticipated by Japanese Application Publication 08-034701 (hereinafter the Shigematsu '701 publication).

With respect to claims 1 and 7 of the instant application, the Shigematsu '701 publication discloses an organ perfusate composition for organ preservation by maintaining the property and function of said organ on a cellular level, wherein said organ perfusate composition comprises an inulin (Detailed Description: [0003], [0004], [0009], [0019]; Industrial Application; Effect of the Invention; Means for Solving the Problem: [0019]; Claims: 1 and 3). With respect to claims 8-11 of the instant application, the Shigematsu '701 publication discloses a method for organ preservation by maintaining the property and function of said organ on a cellular level, wherein said method comprises perfusing said organs with an organ perfusate composition comprising an inulin; wherein said organs include, but are not limited to, a mammalian liver, kidney, spleen and brain (Detailed Description: [0003], [0004], [0009], [0019]; Industrial Application; Effect of the Invention; Means for Solving the Problem: [0019]; Claims: 1 and 3). With respect to claims 12, 16 and 17 of the instant application, a recitation of an intended future use of the claimed invention must result in a patentably distinct difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art composition is capable of performing the intended use of the claimed invention, then the prior art composition anticipates the claimed invention. Since the Shigematsu '701 publication discloses a composition containing ingredients identical to those of the instantly claimed invention, the prior art composition is capable of performing the intended future use of the instantly claimed invention. As a result, the Matsumoto '965 publication anticipates said claims.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 5 and 6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Japanese Application Publication 06-040801 (hereinafter the Wada '801 publication) in view of Japanese Application Publication 05-038284 (hereinafter the Takama '284 publication).

With respect to claims 1, 5 and 6 of the instant application, the Wada '801 publication teaches an organ transplant preservation solution comprising: raffinose and/or hydroxyethyl starch present at a concentration from 0 g/L to 80 g/L; sodium cation present at a concentration from 10 mM to 140 mM; potassium cation present at a concentration from 4 mM to 140 mM; magnesium cation present at a concentration from 0 mM to 4 mM; calcium cation present at a concentration from 0 mM to 2 mM; hydrogen phosphate anion or dihydrogen phosphate anion present at a concentration from 12 mM to 65 mM; and at least one component present at a concentration from 15 mM to 150 mM and selected from the group consisting of: chloride anion; carbonate anion; hydrogen carbonate anion; organic acids; and organic anions. Although the Wada '801 publication teaches utilizing raffinose at a concentration from 0 g/L to 80 g/L within said organ transplant preservation solution, the Wada '801 publication does not explicitly teach

utilizing an inulin fructan at a concentration from 0 g/L to 80 g/L within said organ transplant preservation solution.

However, the Takama '284 publication teaches a liquid preservation composition for preserving living mammalian cells comprising an inulin fructo oligosaccharide or a mixture of inulin fructo oligosaccharides, such as 1-ketose, nistose and furanosyl nistose, *as opposed to raffinose* (Detailed Description: [0001], [0005]-[0015], Effect of the Invention; Means: [0011], [0014]; Claims 1-3). It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to substitute in place of raffinose, within the organ transplant preservation solution of the Wada '801 publication, an inulin fructan or a mixture of inulin fructo oligosaccharide, such as 1-kestose, nistose and/or furanosyl nistose, as reasonably suggested by the Takama '284 publication. One of ordinary skill in the art at the time the instant application was filed would have been motivated and had a reasonable expectation of success in substituting a mixture of an inulin fructo oligosaccharide or a mixture of inulin fructo oligosaccharides, such as 1-kestose, nistose and/or furanosyl nistose, in place of raffinose within the organ transplant preservation solution of the Wada '801 publication, because the Takama '284 publication explicitly teaches not only that the synthesis of raffinose is impossible (therefore causing the commercial availability of raffinose to be restricted and thereby rendering the purchase of raffinose expensive), but also the interchangeability of an inulin fructo oligosaccharide or a mixture of inulin fructo oligosaccharides, such as 1-kestose, nistose and/or furanosyl nistose, with raffinose within the organ transplant preservation solution.

Conclusion

Claims 1-17 are rejected because the claimed invention is anticipated since each and every element of the claimed invention, as a whole, is disclosed in the cited prior art references. Official translations of the aforementioned cited Japanese Application Publications that are relied upon in the construing the claim rejections set forth hereinabove are forthcoming and once received, will be forwarded to the Attorney of Record.

Remarks

The following is a list of prior art patents made of record and considered pertinent to the applicant's disclosure, but are not however currently relied upon in construing the claim rejections as set forth herein:

Japanese Application Publication 09-255501 (hereinafter the Yoshimizu '501 publication).


Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, Esq. whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Sreenivasan Padmanabhan can be reached at 571-272-0629. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see <http://pair-direct.uspto.gov>. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David P. Stitzel, Esq.



MICHAEL HARTLEY
PRIMARY EXAMINER